EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Two new medicines recommended for the treatment of chronic hepatitis C

Additional treatment options with high cure rates to be available to patients

The European Medicines Agency (EMA) has recommended a marketing authorisation for Exviera (dasabuvir) and Viekirax (ombitasvir + paritaprevir + ritonavir) for the treatment of chronic hepatitis C virus (HCV) infection in adults in combination with other medicinal products for the treatment of chronic hepatitis C.

HCV infection is a major European public health challenge. It affects between 0.4% and 3.5% of the population in different European Union (EU) Member States and is the most common single cause of liver transplantation in the EU.

Exviera and Viekirax belong to a new generation of medicines for chronic HCV infection that have high cure rates and have recently reshaped the way this disease is treated. Both Exviera and Viekirax block the action of proteins which are essential for HCV replication. Exviera targets the protein NS5B while Viekirax targets the proteins NS5A and NS3/4A.

This new generation of medicines allows cure of patients with chronic HCV infection without the need for interferons. Until recently, interferons were part of all treatment regimens for chronic HCV infection; these medicines can cause severe side effects that rule out their use in a considerable proportion of HCV patients.

Over the last year, the Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisations for four new medicines for the treatment of HCV. In this area, the more treatment options that are available, the better chance a patient has to get the right treatment to cure the disease and to lead a longer and healthier life.

Both Exviera and Viekirax were evaluated under EMA's accelerated assessment mechanism, a tool which aims to speed up patients' access to new medicines where there is an unmet medical need.

For both medicines, the applicant received scientific advice from EMA in relation to quality, non-clinical and clinical aspects.

The opinion adopted by the CHMP at its November 2014 meeting is an intermediary step on Exviera and Viekirax's path to patient access. The CHMP opinion will now be sent to the European Commission

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

for the adoption of a decision on an EU-wide marketing authorisation. Once marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for both Exviera and Viekirax is AbbVie.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu